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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ABBOTT DIABETES CARE INC. and ABBOTT LABORATORIES

Plaintiffs/Counterdefendants,

v.

ROCHE DIAGNOSTICS CORPORATION, ROCHE DIAGNOSTICS OPERATIONS, INC. and BAYER HEALTHCARE LLC,

Defendants/Counterplaintiffs.

CASE NO. 05-CV 3117 MJJ (BZ)

DEFENDANTS BAYER AND ROCHE'S JOINT MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF THE '745 PATENT

Date: December 12, 2007
Time: 10:00 a.m.
Place: Courtroom 11, 19th Floor
Judge: Hon. Martin J. Jenkins

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I. INTRODUCTION

Defendants Bayer Healthcare LLC ("Bayer"), Roche Diagnostics Corp. and Roche Diagnostics Operations, Inc. ("Roche") (collectively "defendants") move for summary judgment of invalidity of U.S. Patent No. 6,592,745 (the "'745 Patent") on the following grounds:

1) Claim 28 of the '745 Patent, the only claim asserted against Bayer, is anticipated by U.S. Patent No. 6,071,391 (the "Gotoh Patent"), as well as by strips developed by Cambridge Sensors Ltd. ("CSL") and used at Bayer's facilities in Indiana in April 1998;

2) All of the asserted claims (except for claim 11) are anticipated by WO98/35225 (the "'225 reference");

3) Claim 11 is obvious in light of the '225 reference in combination with any one of a number of other references in the prior art;

4) All of the asserted claims are invalid under 35 U.S.C. § 112 because the full scope of the claims is not enabled, and the term "measurement zone" is indefinite.

II. BACKGROUND

The '745 Patent involves disposable test strips that are used with meters to determine blood glucose concentration. The sample chamber of these test strips includes at least two electrodes, commonly called a working electrode and a counter electrode. (Ex. 1 ('745 Patent) at 7:61-67.)[1] The sample chamber also contains at least two different chemicals, namely, a mediator and an enzyme (collectively known as "reagents"). (*Id*. at Abstract [57].) When blood enters the sample chamber, the enzyme catalyzes a chemical reaction during which the glucose molecules give up electrons that are picked up by the mediator. This "redox" reaction causes the blood glucose molecules to lose electrons ("oxidize") and the mediator molecules to gain electrons ("reduce"). When the meter applies a potential, the reduced mediator molecules that diffuse to the working electrode transfer their electrons to (are "electro-oxidized" by) the working electrode. The meter determines the glucose concentration by measuring this electro-oxidation.

[1] All references to exhibits are attached to the Declaration of Parisa Jorjani in Support of Defendants Bayer and Roche's Joint Motion for Summary Judgment of Invalidity of the '745 Patent.

The '745 Patent discloses three ways to determine the concentration of glucose in whole blood: coulometry, potentiometry, and amperometry. (Ex. 1 ('745 Patent) at Abstract [57], 6:12-13, 6:20-29, 7:19-21.) In a coulometric test, the glucose concentration is determined by totaling up the *charge* derived from all of the glucose in a defined volume. (*Id.* at 6:20-29.) In an amperometric test, the glucose concentration is determined by measuring the *current*, *i.e.* the rate of flow of the electrons, from the volume above the working electrode, with the magnitude of the current being proportional to the concentration of glucose. (Ex. 2 (Bard Dep. 10/18/2007) at 291:9-292:11.) Claim 28 of the '745 Patent is limited to amperometric testing. (Ex. 1 ('745 Patent) at 65:1-2.)

The '745 Patent also discloses at least two different ways of configuring the electrodes. The electrodes can be placed on the same substrate such that they are in a "co-planar" configuration. (Ex. 1 ('745 Patent) at 3:31-33, 3:51-54, Fig. 2.) The electrodes can also be on separate substrates in a facing configuration. (*Id.* at 3:18-24, 3:46-50, Fig. 1.) The claims are not limited to a specific electrode configuration.

The reaction in glucose test strips can also produce a current from sources other than glucose, which may adversely affect the accuracy of the measurement. This current is generally called a background signal. (Ex. 3 (Claim Construction Order, filed 4/27/2007) at 25.) The '745 Patent is focused on limiting a certain type of background signal, specifically that resulting from mediator shuttling. Shuttling occurs when a mediator that has given up its electron at the working electrode diffuses to the counter electrode, picks up an electron there that does not come from glucose, then travels back to the working electrode and gives it up there. (*Id.* at 27.) As defined by the '745 Patent and interpreted by the Court shuttling is the only background signal in the claims. (*Id.* at 25.)

III. LEGAL STANDARD

Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ . P. 56(c). In the case of an anticipation defense, courts should grant summary judgment where, as here, the undisputed facts show that the prior art meets the limitations of the claim at issue. *See Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001). To meet the limitations of the disputed

claim, the anticipating prior art need not use the same language as the patent-in-suit; rather, it is simply necessary that the elements of the claim be part of a single prior art reference. *See Helifix, Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346-47 (Fed. Cir. 2000).

Summary judgment on the invalidity of a patent claim is also warranted when the claim is not supported by an enabling disclosure. *See e.g., Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1198 (Fed. Cir. 1997) (affirming summary judgment of invalidity for lack of enablement). A court considering a motion for summary judgment must consider the burden on the patent specification to teach "those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*, 99 F.2d 1557, 1561 (Fed. Cir. 1993).

IV. ANALYSIS

A. The Gotoh Patent Invalidates Claim 28 of the '745 Patent

The Gotoh '391 Patent was filed on December 15, 1997, before Plaintiff's earliest alleged conception date, and is prior art under 35 U.S.C. § 102(e). (Ex. 4 (Gotoh Patent) at [22]; Ex. 5 (Abbott's Supp. Resp. 9/12/2007) at 3 (alleging conception date of July 30, 1998)). Gotoh discloses at least two examples of test strips that meet every limitation of claim 28 of the '745 Patent. Example B1 of Gotoh describes a blood glucose test strip with working and counter electrodes separated by 140 μm (microns), and enzyme and mediator placed on the working electrode. A 1 μL (microliter) sample was added to the strip, and, after a 20-second rest period, a potential was applied for 10 seconds. The current was then measured, and the strip achieved an accuracy level in line with commercial strips. (Ex. 6 (Bard Dep. 10/19/2007) at 395:15 - 398:10.) Gotoh Example D1 describes a similar strip with electrodes spaced 230 μm apart. As explained below, these strips practice the method of claim 28. Representative figures are attached as Appendix A.

As stated in **the preamble of claim 28,** the Gotoh Patent discloses a "method for determining a concentration of glucose in a sample." (*See* Ex. 4 (Gotoh Patent) at 1:44-58.)

As required by **claim 28 (a)**, the Gotoh Patent discloses "contacting a sample with an electrochemical sensor." (*See* Ex. 4 (Gotoh Patent) at 8:24-39, 12:34-50.)

As required by **claim 28 (a)(i)**, the Gotoh patent discloses working and counter electrodes "separated by a closest distance no greater than 1000 µm." In examples B1 and D1, both of which have electrodes in a facing configuration, the distance between the electrodes is 140 µm and 230 µm, respectively.[2] (Ex. 4 (Gotoh Patent) at 7:56-8:10, 12:4-33.)

Claim 28 (a)(ii) requires a "measurement zone … sized to contain a volume of no more than about 1 µL of the sample." The '745 Patent defines "measurement zone" as "a region of the sample chamber sized to contain only that portion of the sample that is to be interrogated during an analyte assay." (Ex. 1 ('745 Patent) at 7:7-9.) Abbott stipulated to this definition in the claim construction process.[3] Examples B1 and D1 each disclose methods using a *total* sample volume of 1 µL. (Ex. 4 (Gotoh Patent) at 8:24-26, 12:34-36.) The maximum amount of sample "interrogated" cannot be larger than the 1 µL of volume present in the Gotoh strips. Because the measurement zone is sized to contain a "***portion*** of the sample that is to be interrogated," and the *total* sample volume is 1 µL, the measurement zone in Examples B1 and D1 must be within the 1 µL claim limitation. (*See* Ex. 3 (Claim Construction Order) at 22 (emphasis added)).

Abbott itself stated in its Final Infringement Contentions that "[t]he measurement zone cannot be larger than the total amount of blood in the strip."[4] (Ex. 10 (Final Infringement Contentions – Bayer 5/29/2007) at Ex. 2, p. 3.) Abbott's expert, Dr. Allen Bard, reiterated this position both in his expert report and in his deposition. (*See* Ex. 8 (Bard Report 9/12/2007) at 8; Ex. 6 (Bard Dep.) at 313:23 - 314:18; Ex. 2 (Bard Dep.) at 250:1-4.) Dr. Bard nonetheless argues that it is unclear whether the Gotoh Patent discloses a strip that has a measurement zone of just 1 µL of sample. He postulates that the measurement zone in strips B1 and D1 could be larger than the sample and "may

[2] The 140 µm electrode spacing in Example B1 is calculated by subtracting 20 µm (thickness of two 10 µm carbon electrodes) from 160 µm (thickness of the adhesive tape). The electrode spacing in Example D1 is calculated in the same way except that the thickness of the spacer is 250 µm (0.25 mm), resulting in 230 µm. Dr. Bard equates the electrode distance with the *total* spacer height, which is also under 1000 µm (*see* Ex. 7 (Bard Rebuttal 10/5/2007) at 22).

[3] Ex. 9 (Claim Construction Statement, filed 10/24/2006), Exh. 2 at 1.

[4] Claims are construed the same way for both invalidity and infringement. *Eaton Corp. v. Rockwell Int'l Corp.,* 323 F.3d 1332, 1343 (Fed. Cir. 2003).

be only partially filled." (Ex. 7 (Bard Rebuttal) at 21-22.) This does not conform to a plain reading of the '745 Patent, which defines measurement zone as a "portion" of the sample. This is also contrary to Abbott's position that the measurement zone can be no larger than the total sample in the test strip. Thus, the amount of sample "interrogated during the analyte assay" cannot be larger than the 1 μL of volume actually present in Examples B1 and D1.

Dr. Bard's only support for his theory is found in a portion of the Gotoh patent pertaining to Figures 1 through 5 that 0.5 to 10 μL may be applied to a "thus-manufactured glucose biosensor." (Ex. 7 (Bard Rebuttal) at 22, citing Ex. 4 (Gotoh Patent) at 5:37-45.) Dr. Bard believes that the phrase "thus-manufactured strip" may mean a single strip that can accommodate all sample volumes from 0.5 to 10 μL. (*Id.*) The Gotoh patent cannot be so interpreted, for many reasons.

First, the quoted passage does not disclose a single sensor that can accommodate a range of sample sizes of 0.5 to 10 μL. It provides a range of different sensors that can be made. The same paragraph discloses a range of voltages (0.4 to 1.2 V) and test times (1 to 120 seconds) as well. (Ex. 4 (Gotoh Patent) at 5:40-42.) This does not mean that a single "thus-manufactured strip" can operate at the full range of these samples sizes, voltages, and test times. The Gotoh Patent discloses many different embodiments, but never states that the sensor is configured to utilize a wide range of sample sizes.

Moreover, the "thus-manufactured electrode" phrase relied on by Bard does not even apply to all of the embodiments disclosed by Gotoh. In particular, it does not apply to Examples B1 and D1 and their related figures. The Gotoh Patent is divided into sections based on the various figures. The section with the text on which Dr. Bard relies pertains to Figures 1 through 5. (Ex. 4 (Gotoh Patent) at 3:37-6:62.) Example B1, however, is in the section pertaining to Figures 6 through 9. (*Id.* at 6:63-9:5.) Example D1 relates to Figures 11-14. (*Id.* at 9:63-13:34.) Thus, Gotoh does not suggest that the devices disclosed in Examples B1 and D1 may have a measurement zone of more than 1 μL.

Claim 28 (a)(ii) also requires the measurement zone to be "adjacent to the working electrode and the counter electrode." In its Claim Construction Order, this Court defined the term "adjacent" to mean that the "measurement zone is next to (whether or not touching) both the working electrode and

the counter electrodes, with no structure intervening between either electrode and the measurement zone." (Ex. 3 (Claim Construction Order) at 24.) Examples B1 and D1 disclose embodiments having facing electrodes spaced 140 and 230 μm apart, formed by placing a working electrode on one base, a counter electrode on a second base, then spacing the two bases apart using a spacer or double-sided tape. (*See* Ex. 4 (Gotoh Patent) at 7:24-40, 8:1-6, 12:26-33.) There is no disclosure of any "intervening structure" between these electrodes. Moreover, Abbott has stated that the measurement zone in a facing electrode strip is the entire space between the working and counter electrodes and must touch both electrodes.[5] Abbott has not disputed that the Gotoh patent discloses this element. (Ex. 7 (Bard Rebuttal) at 22.)

Claim 28 (a)(iii) requires that an enzyme and diffusible mediator is disposed within the measurement zone. Examples B1 and D1 use an analyte-responsive enzyme (glucose oxidase) and a diffusible mediator (ferricyanide) coated above the working electrode (and therefore in the measurement zone). (*See* Ex. 4 (Gotoh Patent) at 7:58-67, 12:14-21.)

Pursuant to **claim 28(b)**, the test strips disclosed by the Gotoh patent hold the sample within the measurement zone in a non-flowing manner. In the related BD case, the Court construed the term "non-flowing" in a sister patent to mean that the sample is "not moving" during measurement. (Ex. 11 (Claim Construction Order (BD), dated 8/31/2006) at 15-16.)[6] In Example B1, the sample is "allowed to stand for 20 seconds" before the voltage is applied. (*See* Ex. 4 (Gotoh Patent) at 8:24-28.) In Example D1, it is allowed to stand for 80 seconds. (*Id.* at 12:38.) Gotoh also discloses that the sample is "precisely caught" in the strip, teaching that it is not allowed to continue moving at the time of measurement. (*See, id.* 5:62-63.) Accordingly, the sample is "at rest" during the measurement.[7] (Ex. 6 (Bard Dep.) at 411:25 - 412:19, 413:24 - 414:13.)

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[5] *See* Ex. 12 (Abbott's Amended Resp. 7/20/2007) at 3-4; Ex. 10 (Final Infringement Contentions – Bayer) at Ex. 2, p. 3; Ex. 13 (Dep. of E. Heller 8/17/2007) at 572:20 - 573:11; Ex. 14 (30(b)(6) Dep. of Feldman 6/20/2007) at 33:6 - 34:5, 42:17 - 43:8.

[6] Bayer and Roche respectfully request the Court to take judicial notice of this record from the Court's files.

[7] Turner Decl. at ¶ 27; *accord* Ex. 14 (30(b)(6) Dep. of Feldman) at 329:24 - 331:9; Ex. 15 (Dep. of Feldman 8/14/2007) at 280:22 - 281:16; Ex. 13 (Dep. of E. Heller 8/17/2007) at 524:25 - 525:7.

Examples B1 and D1 also meet the requirement of **claim 28(c)** requiring that the background signal generated by shuttling be less than five times the signal generated by an average normal physiological amount of glucose (the analyte). This Court has previously construed the phrase "background signal that is generated by the redox mediator" as "background signal that is created by the shuttling of the redox mediator back and forth between the working and counter electrodes during the measurement period." (Ex. 3 (Claim Construction Order) at 26.) Thus, shuttling requires the mediator molecule to travel from the working electrode to the counter electrode and back again. (*Id.*)

Based on the formula taught by the '745 Patent and the prior art, the electrodes in Examples B1 and D1 of Gotoh are too far apart, and the measurement period is too short, for shuttling to occur. Specifically, according to the '745 Patent, no shuttling will occur when the electrodes are spaced far enough apart:

> [i]n some amperometric . . . embodiments, the redox mediator circulation is decreased by separating the working electrode from the counter or counter/reference electrode such that the distance through which the redox mediator would diffuse during the measurement period is no greater than, for example, the distance between the electrodes. A redox mediator can diffuse a distance equal to $(D_m t)^{1/2}$, where D_m is the effective diffusion coefficient for the medium between the electrodes and t is time.[8]

(Ex. 1 ('745 Patent) at 43:49-57.) According to this teaching, one can use the $(D_m t)^{1/2}$ formula to determine how far the mediator will travel and choose a suitable electrode spacing to avoid shuttling. (*Id.*; see also 49:38-41 ("[i]n some instances, the distance between electrode pairs is sufficient that redox mediator and/or enzyme do not substantially diffuse between electrode pairs during the measurement period …").) The '745 Patent provides an example of how to space the electrodes to diminish shuttling, given a diffusion coefficient between 10^{-5} and 10^{-6} cm^2/s and a test time of 30 seconds. (*Id.* at 43:57-62.) The patent teaches that the electrodes should be at least 100 microns

[8] This equation was known in the art prior to the '745 Patent. (Ex. 14 (30(b)(6) Dep. of Feldman) at 179:15 - 182:10.)

apart. (*Id.*) This same formula can be used to determine whether shuttling occurs in the examples of the Gotoh Patent.[9]

In Gotoh Examples B1 and D1, the distance between the electrodes is 140 µm and 230 µm, respectively. (Ex. 4 (Gotoh Patent) at 7:56-8:10, 12:26-33.) Thus, to shuttle from the working electrode to the counter electrode *and back* as required by the claims, the mediator would need to travel 280 µm in Example B1 and 460 µm in Example D1. (Ex. 14 (30 (b)(6) Dep. of Feldman) at 228:21-229:3.) In both examples, the test time when potential is applied and shuttling may occur is 10 seconds. (Ex. 4 (Gotoh Patent) at 8:24-29, 12:34-39.) The mediator disclosed in Gotoh is ferricyanide, which Abbott has stated has a diffusion coefficient of 7.6×10^{-6} cm^2/s in buffer. (Ex. 6 (Bard Dep.) at 376:25 - 377:6.) Applying the $(D_m t)^{1/2}$ formula, the mediator in the Gotoh strips would diffuse a distance of approximately 87 µm during the 10-second measurement period in buffer. Thus, according to the teaching of the '745 Patent, the mediator would not travel far enough during the measurement period to cause any shuttling. (Turner Decl. ¶29.) The lack of shuttling is confirmed by the fact that when the electrodes in Gotoh Example D1 were moved from 230 to 140 µm apart, there was no increase in current signal: the average measurement was 24.0 µA at 230 µm and 23.7 µA at 140 µm.[10] (Ex. 4 (Gotoh Patent) at 12:49, 13:24.)

Dr. Bard takes issue with the use of the $(D_m t)^{1/2}$ formula from the '745 Patent to determine the presence of background signal. (Ex. 7 (Bard Rebuttal) at 12-16.) However, Plaintiff's expert theories cannot change the teachings of the patent, which specifically uses $(D_m t)^{1/2}$ to determine the electrode spacing required to avoid shuttling. (Ex. 1 ('745 Patent) at 43:49-57.) None of the complicated analysis presented by Dr. Bard on this issue is disclosed in the '745 Patent. (*Compare* Ex. 7 (Bard Rebuttal) at 13-16 with Ex. 1 ('745 Patent) at 43:49-57.) His analysis is therefore completely inapplicable.

[9] Abbott has admitted that this solution to shuttling was known in the art prior to the '745 Patent. (*See* Ex. 14 (30(b)(6) Dep. of Feldman) at 246:19 - 248:11; Ex. 2 (Bard Dep.) at 118:18 - 121:6.)

[10] The 140 µm electrode distance is calculated by subtracting 20 µm (thickness of two 10 µm carbon electrodes from 160 µm (thickness of the adhesive tape used in Example D3).

In any event, even using Dr. Bard's modified formula ($2(D_m t)^{1/2}$) for calculating background signal, Gotoh examples B1 and D1 meet element 28(c). Dr. Bard used this modified formula to determine that shuttling did not occur in the accused devices for purposes of infringement. (Ex. 6 (Bard Dep.) 376:17-24.) He has stated that this is a "somewhat better" formula for the shuttling calculation. (Ex. 7 (Bard Rebuttal) at 15-16.) Using Bard's modified formula and Abbott's diffusion coefficient, the mediator in the Gotoh test strips diffuses only 174 µm in 10 seconds.[11] As discussed above, to shuttle from the working electrode to the counter electrode and back, the mediator would need to travel 280 µm in Example B1 and 460 µm in Example D1 of Gotoh. Thus, even using Dr. Bard's modified formula, the mediator cannot make the required round trip back to the working electrode to contribute to the background signal due to shuttling.

Finally, as required by **claim 28 (d),** Examples B1 and D1 disclose determining the concentration of the glucose using current, *i.e.*, by amperometry. (*See* Ex. 4 (Gotoh Patent) 8:28, 12:38.)

Accordingly, the Gotoh reference meets all elements of Claim 28.

B. The CSL Strip Invalidates Claim 28 of the '745 Patent.

Claim 28 of the '745 Patent is also rendered invalid by the CSL test strips under 35 U.S.C. §102 (g). CSL is a UK company headed by James McCann that develops and manufactures blood glucose test strips, including a strip currently sold in the United States. (Ex. 16 (CSL website, dated 7/13/2007) at BAYER0402567 to -68 & -71 to -72.) In April 1998, a CSL employee, Neil Blair, brought a batch of its glucose test strips (bearing lot number 7J2210) to Bayer's laboratories in Indiana. (Ex. 17 (McCann Dep. 7/19/2007) at 46:25-47:24.) On April 28 and 29, 1998, these strips were used at Bayer to measure the glucose concentration in whole blood of 36 diabetic patients. (Ex. 17 (McCann Dep.) at 47:23-48:23; Ex. 18 (Blair Dep.) at 12:20-19:1; Ex. 19 (McCann Def. Dep. Ex.

[11] Dr. Bard uses a test time of 20 seconds in his calculations. (Ex. 7 (Bard Rebuttal) at 14.) However, Gotoh states that the measurement is made "10 seconds from the application" of the voltage. (Ex. 4 (Gotoh Patent) at 8:24-29, 12:34-39.) Thus, the relevant time is 10 seconds, not 20. (Ex. 6 (Bard Dep.) at 396:18-397:18; Ex. 2 (Bard Dep.) at 61:10 - 62:6.) Regardless, there is no shuttling even at 20 seconds: the mediator in the Gotoh strips diffuses only 246 µm using Bard's formula at 20 seconds.

247).) Accordingly, the method of the CSL strips was practiced in the United States before Abbott's invention date and was reduced to practice before that date.[12]

1. The CSL Strip Meets Every Limitation of Claims 28 of the '745 Patent.

When used in April 1998, the CSL strips met all of the elements of Claim 28, as follows:

Claim 28 preamble. The CSL strips were used in a "method for determining a concentration of glucose." (Ex. 17 (McCann Dep.) at 47:23-48:23; Ex. 19 (McCann Def. Dep. Ex. 247).)

Claim 28(a). The CSL strips contacted blood samples. (*Id.*)

Claim 28 (a)(i). The distance between the working and counter electrodes on the CSL strips is less than 1000 µm. Specifically, the working electrode in the CSL strip is comprised of a carbon conducting layer with mediator and a reagent layer deposited on top. (Turner Decl. ¶¶ 39-40.) The CSL strip also includes a counter electrode comprised of a carbon conducting layer with a square of silver-silver chloride ("Ag/AgCl") deposited on top. (*Id.*) The carbon conducting layers of the two electrodes are separated by a closest distance of approximately 500 µm. (Ex. 17 (McCann Dep.) at 60:15-64:7.) This is consistent with measurements made on an actual CSL strip from the lot brought to Bayer in April 1998, in which the electrode distance was determined to be approximately 538 µm. (Turner Decl. ¶¶ 45-46; Stetter Decl. ¶¶ 32-34; (Ex. 17 (McCann Dep.) 46:25-47:22, 58:10-59:16.)

Claim 28 (a)(ii). The CSL strips had a total sample chamber volume of no more than about 1 µL. (Ex. 17 (McCann Dep.) at 78:8-83:15; Turner Decl. ¶¶ 37; 55.) Because the measurement zone in the '745 Patent is by definition a "region" of the sample chamber and a portion of the sample, *see* Ex. 1 ('745 Patent) at 7:7-9, the measurement zone of the CSL test strip also must have a volume of less than 1 µL.[13] The CSL strip also does not have any structure intervening between the working

[12] Abbott has recently asserted an earliest conception date of July 30, 1998. (Ex. 5 (Abbott's Supp. Resp.) at 3.) The CSL strips were reduced to practice before that date when they were used in the United States in April 1998. *Shurie v. Richmond*, 699 F.2d 1156, 1158 (Fed. Cir. 1983) (a process is not reduced to practice in the United States unless it is performed in this country); *Scott v. Koyama*, 281 F.3d 1243, 1247 (Fed. Cir. 2002) (same); *Boston Sci. Corp v. Johnson & Johnson*, 481 F. Supp. 2d 1018, 1028 (N.D. Cal. 2007) ("processes must be performed in the United States to be actually reduced to practice.").

[13] Abbott stipulated to this definition in the claim construction process. (Ex. 9 (Claim Construction Statement) at Exh. 2 at 1).

and the counter electrodes. (Ex. 20 (Def. Dep. Exs. 249 & 250); Turner Decl. ¶ 36.) Abbott has not disputed that the CSL strip meets these limitations. (Ex. 7 (Bard Rebuttal) at 25.)

Claim 28 (a)(iii). The CSL strip has an "analyte-responsive enzyme" (glucose dehydrogenase) and a "diffusible redox mediator" (medola blue) on the working electrode and therefore in the measurement zone. (Ex. 17 (McCann Dep.) at 22:15-23:6; 26:14-21.)

Claim 28 (b). The CSL strip was used in a "non-flowing manner." (Ex. 18 (Blair Dep.) at 36:18-24.)

Claim 28 (c). Tests performed by CSL demonstrate that the CSL test strips met the background signal limitation of claim 28 of the '745 Patent.[14] Because the *total* background signal for those strips is less than five times the signal generated at approximately a normal physiological amount of glucose, the CSL test strip meets the ratio required by claim 28 of the '745 Patent. (*Id.*) Abbott has not disputed that the CSL strip meets this limitation of claim 28. (Ex. 7 (Bard Rebuttal) at 25; Ex. 6 (Bard Dep.) at 394:9-11.)

Claim 28 (d). The CSL strips used amperometry. (Ex. 22 (BAYER0397609-10; 0266791-96).)

2. Abbott's Argument Is Based on Faulty Measurements and Should Be Disregarded.

Abbott concedes that the CSL strips met all but only one element of claim 28: element (a)(i), that the closest distance between the working and counter electrodes in the CSL strips must be no more than 1000 µm. Abbott alleges that the distance between the working and counter electrodes in the CSL strip is 1150 µm. (Ex. 7 (Bard Rebuttal) at 25.) Abbott's argument fails to raise a genuine issue of fact because Abbott measured the wrong dimension of the CSL strip.

The relevant distance under claim 28(a)(i) is the distance between the working electrode and the counter electrode. Instead of measuring this dimension, Abbott measured the distance between

[14] *See* Ex. 18 (Blair Dep.) 19:2-21:15; 24:13-35:1 & (Ex. 21 (Def. Ex. 285) (showing total background signal of 0 in buffer and 0.4 nA in whole blood, and normal signal of 1.12 nA); Turner Decl. ¶ 60 & Table 3.

the reagent layer deposited on the working electrode and the Ag/AgCl layer deposited on the counter electrode. (Ex. 7 (Bard Rebuttal) at 25.)

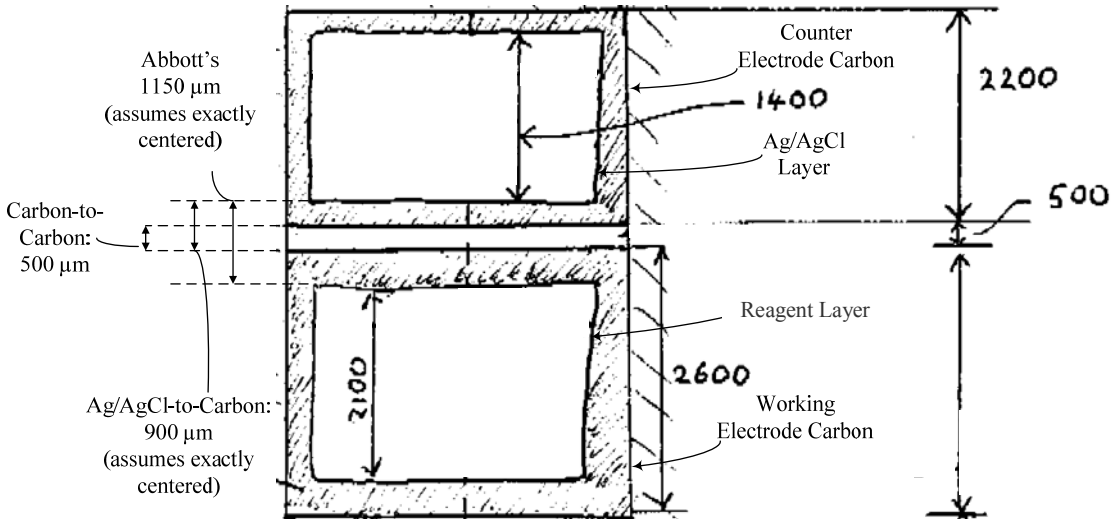

Figure 1

As shown in Figure 1 above, the working and counter electrodes include *both* a carbon layer and a reagent and Ag/AgCl layer, respectively. Abbott does not contest that the distance between the carbon layers of the working and counter electrodes in the CSL strip is less than 1000 µm. Moreover, the patent discloses that the conducting layer (*e.g.* carbon) is part of the working electrode. (Ex. 1 ('745 Patent) at 8:8-15, *see also* at 59:1-8 (describing placing reagent on only "a portion of" the working electrode).) Even using Abbott's alleged "measurements," the distance from the Ag/AgCl layer on the counter electrode and the carbon on the working electrode is less than 1000 (specifically, 900 µm). (*See* Fig. 1 above.) Thus, using the correct definition of working electrode and Abbott's measurement, the distance is still less than 1000 µm.

Abbott's argument is also unsupported by actual evidence, because Abbott did not actually measure the prior art CSL strips (which were provided to Abbott). Instead, Abbott relied on a drawing done by one of the CSL inventors that was expressly a not-to-scale "sketch." (Ex. 17 (McCann Dep.) at 68:15-20.) Based on the not-to-scale sketch, Abbott *assumes* that the layers on the electrodes are exactly centered onto the carbon portions of the electrodes. But it is plain from an actual photograph of a CSL strip that the reagent layers are *not* centered on the carbon. (Turner Decl.

Ex. C.) As explained in the Turner Declaration, measurements of the actual CSL strip show that the distance between the electrodes is less than 1000 µm regardless of whether one measures the distance between the carbon layers, the distance between the Ag/AgCl of the counter and the carbon of the working electrode, or even, as Abbott proposes, the distance between the Ag/AgCl and the reagent layer on top of the working electrode. (Turner Decl. ¶ 47).

3. CSL Did Not Abandon, Suppress, or Conceal the Method of Using the Strips Under 35 U.S.C. Section 102(g).

Once defendants show with clear and convincing evidence that CSL was the first to reduce the methods to practice in the United States, the burden shifts to Abbott to produce evidence sufficient to create a genuine issue of material fact as to whether CSL abandoned, suppressed, or concealed the invention. *Apotex USA Inc. v. Merck & Co. Inc.*, 254 F.3d 1031, 1037-38 (Fed. Cir. 2001).

In connection with the development of its glucose strips, CSL filed several patent applications, and was granted at least one United States Patent.[15] Moreover, CSL consistently engaged in negotiations with various business partners in an effort to manufacture and sell its novel glucose strip. Specifically, CSL approached a number of companies to serve as potential partners, including Abbott. (Ex. 17 (McCann Dep.) at 27:13-36:12.) In 1998 CSL developed a partnership with Becton Dickinson (one of the defendants in this case) to commercialize its strip. (*Id*. at 92:15-93:11, 95:11-102:25, 106:1-23.) The partnership lasted for over two years, during which CSL worked to bring its strip to market under Becton Dickinson's specifications. (*Id.*) In 2001, CSL developed a business partnership with CHDiagnostics, the company which ultimately brought the CSL strip to market in 2003 (sold under the SeNova brand).[16] The SeNova strip meets the limitations of claim 28 of the '745 Patent. (Turner Decl. ¶¶ 64-66.) Thus, the CSL strip was not abandoned, suppressed or concealed. *Apotex*, 254 F.3d at 1037-38; *Checkpoint Sys., Inc. v. U.S. Int'l Trade Comm'n*, 54 F.3d 756, 761 (Fed. Cir. 1995).

[15] *See, e.g.*, Ex. 26 (WO98/55856); Ex. 27 (WO0028068); Ex. 28 (U.S. Pat. No. 6,436,256); Ex. 29 (US2006/0287035).

[16] Ex. 17 (McCann Dep.) at 103:1-105:25; 108:2-109:8; Ex. 16 (CSL website); Ex. 30 BAYER0402570 (FDA 510(k) for SeNova).

C. The Heller '225 Reference Anticipates All But One Asserted Claim of the '745 Patent.

Roche submitted the expert report of Stephen G. Weber, Ph.D., in support of its position that the '745 patent is invalid because it was anticipated and obvious. In his report, Dr. Weber concluded that all of the asserted claims of the '745 Patent, except claim 11 (which is obvious as shown below), are anticipated under 35 U.S.C. § 102(a) by at least WO98/35225, a published patent application ("Heller '225 reference"). (Weber Dec. at Ex. 1: 42-46.)[17] The Heller '225 reference was published on August 13, 1998, before the earliest filing date of the '745 Patent. (*Id.*) Abbott's expert, Dr. Bard, admits that the Heller '225 reference contains the same disclosure as the '164 Patent. (Ex. 7 (Bard Rebuttal Report) at 24 and Ex. 2 (Bard Dep.) at 144:23 - 145:2.) In the text of his report and an accompanying claim chart, Dr. Weber analyzed every element of the asserted claims and, except for claim 11, found them all present in the Heller '225 reference.[18] (Weber Dec. Ex. 1 at 42-46 and '225 claim chart.)

In response, Abbott's expert, Dr. Bard, did not dispute that the '225 reference discloses all the elements of all the asserted claims of the '745 Patent. Dr. Bard's only response related to the diffusible redox mediator element, as to which he stated:

> In my opinion, reasonable minds can differ about whether the '164 Patent discloses the use of diffusible mediators. Dr. Weber appears to believe that the '164 Patent does disclose their use (see his discussion of the PCT equivalent to the '164), while Dr. Turner appears to believe that there is no such disclosure. One of ordinary skill in the art could make a sensor with diffusible mediators using the teachings of the '164 Patent whether the '164 Patent explicitly discloses them or not.

(Ex. 7 (Bard Rebuttal) at 24.) For the reasons given below, Dr. Bard's response concedes the invalidity of the '745 Patent.

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[17] This motion is supported by a Declaration of Dr. Weber that verifies his invalidity report.

[18] Dr. Weber concluded that claim 8 of the '745 patent is disclosed by the Heller '225 reference but that the disclosure is not enabling. In the next section of this brief, Defendants demonstrate that the '745 patent is invalid because the specification does not enable the full scope of the claims. If the Court disagrees with that argument, then claim 8 of the '745 patent is likewise anticipated by the Heller '225 reference.

At his recent deposition, Dr. Bard admitted that his report does not say that Dr. Weber "was wrong about anything" when Dr. Weber concluded that the Heller '225 reference anticipates the '745 Patent. (Ex. 2 (Bard Depo.) at 158:14-24.) Dr. Bard admitted that the Heller '225 reference discloses that diffusible mediators can be used, although they are not preferred. (*Id*. at 141:23-25, 142:9-143:5.) When specifically asked to identify anything inventive in the '745 Patent that was not already included in the Heller '225 reference, Dr. Bard did not identify a diffusible mediator. (*Id*. at 203:25 – 205:3.) Further, Dr. Bard agreed that none of the items he did identify are elements of the asserted claims of the '745 Patent. (*Id*. at 207:18 – 208:23 (air oxidizable mediator and using applied potential of zero volts are not claim elements).) Thus, between his report and his deposition testimony, Dr. Bard has conceded that the Heller '225 reference includes all the elements of, and therefore invalidates, the asserted claims of the '745 Patent.

Although Dr. Weber's analysis coupled with Dr. Bard's failure to dispute it should end the matter, the Heller '225 reference in fact expressly discloses a diffusible mediator:

> More preferably, the redox mediators of the present invention are bound or otherwise immobilized on the working electrode 22 to prevent undesirable leaching of the mediator into the sample. *A diffusing or leachable (i.e., releasable) redox mediator* is not desirable when the working and counter electrodes are close together. . . .

(Ex. 23 ('225 reference) at 9:25-29 (emphasis added).)[19] A reference anticipates an invention even if, after disclosing the invention, the reference then disparages it. *Upsher-Smith Labs., Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1323 (Fed. Cir. 2005); *Celeritas Techs., Ltd. v. Rockwell Int'l Corp*., 150 F.3d 1354, 1361 (Fed. Cir. 1998)). Thus, "the question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis." *Id.* Given the Heller '225 reference's express disclosure of a diffusible mediator, Dr. Bard's report cannot create a genuine issue of material fact to

[19] The '225 reference also discloses that "almost any organic or organometallic redox species can be used as a redox mediator," such as, for example, Nile blue, indophenol, quinones and quinhydrones, including ferricyanide. (Ex. 23 ('225 reference) at 10:13-25, 11:14). In the '225 reference, independent claim 127 calls for a "redox mediator on its working electrode" and its dependent claim 128 states that the redox mediator is a non-leachable mediator, implying that redox mediator in claim 127 necessarily includes a leachable mediator. (*Id*. at 63). The claims of a patent are part of its specification and disclosure. 35 U.S.C. § 112; *In re Dossel*, 115 F.3d 942, 945 (Fed. Cir. 1997).

preclude summary judgment. Further, as noted above, Dr. Bard has admitted that the Heller '225 reference discloses a diffusible mediator.

Additionally, Abbott is judicially estopped from denying that the Heller '225 reference discloses a diffusible mediator. During the Markman proceedings in the related cases against Becton Dickinson and Nova Biomedical, Abbott argued that claim 16 of the '164 Patent could not be limited to an immobilized mediator because an immobilized mediator was simply a preferred embodiment, *i.e.*, other embodiments had diffusible mediators. *See* Docket No. 189-1 in Case No. 3:04-cv-02123-MJJ at 16-17 ("The specification makes clear that immobilized mediators are aspects of preferred embodiments. . . . It is likewise irrelevant that the patent expresses a strong preference for immobilized mediators. . . . [I]dentification of an option as inferior is not enough to exclude it from the scope of the claim.").[20] To have "identified" an option of using immobilized mediators, the '164 Patent must have disclosed diffusible mediators. Similarly, in the slides for the Markman hearing on the '164 Patent, to support its position that "[i]mmobilized mediators are merely preferred" in the '164 Patent/Heller '225 reference, among other passages from the '164 Patent Abbott cited Column 6 at lines 26-30, the same passage from the Heller '225 reference quoted above that expressly discloses a diffusible mediator. (Ex. 24 (Abbott's 164 Markman slides) at Slide 64.) Abbott prevailed on its argument that immobilized mediators were simply a preferred embodiment, such that claim 16 of the '164 patent covered other mediators as well, including diffusible mediators. (Ex. 11 (Claim Construction Order) at 14.)[21] When agreeing with Abbott's argument, the Court also relied on the language from the '164 Patent/Heller '225 reference that expressly discloses a diffusible mediator and is set out above. (*Id.*)

Having successfully urged the position that the '164 Patent/Heller '225 reference discloses and covers diffusible mediators, Abbott is judicially estopped from contending otherwise now. "'Judicial estoppel' applies when a party takes a later position that is inconsistent with a former

[20] Bayer and Roche respectfully request the Court to take judicial notice of this record from the Court's files.

[21] Bayer and Roche respectfully request the Court to take judicial notice of this record from the Court's files.

position in the same dispute, on which the party had been successful and had prevailed based on the former position." *Bonzel v. Pfizer, Inc.*, 439 F.3d 1358, 1362 (Fed. Cir. 2006); *see also Transclean Corp. v. Jiffy Lube Int'l, Inc.*, 474 F.3d 1298, 1307 (Fed. Cir. 2007) ("the underlying purpose of the doctrine is to protect the integrity of the judicial process."); *U.S. v. Lence*, 466 F.3d 721, 726 (9th Cir. 2006). Because Abbott prevailed on its earlier position, it is judicially estopped from asserting a contrary position.

D. The Asserted Claims are Obvious as a Matter of Law.

To the extent that any element is found to be missing from the Gotoh Patent, the CSL strip, or the Heller reference, it would have been obvious to a person of ordinary skill in 1998 to combine the references. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S. 2007).[22] All of these references relate to the same field, specifically glucose sensors, and a person of skill in the art in 1998 would have been motivated to combine them to practice the methods of the '745 Patent. A person of skill in the art would have been motivated to measure glucose concentration using a sensor having a very low background such as the CSL strip, having a small volume such as the CSL and Gotoh strips, and having electrodes separated by a small distance, such as the Gotoh strip.

In particular, claim 11 of the '745 patent adds to claim 1 the further limitation that the glucose concentration is determined "by a measurement technique from the group consisting of chronoamperometry and Cotrell-type measurement techniques using the sensor signal." (Ex.1 ('745 Patent) at 62:59-62.) In his report, Dr. Weber stated that each of the other four references he applied against claim 11 taught this element. (Weber Dec. at Ex. 1, 56-58.) In the claim chart for the Heller '225 reference attached to his report, Dr. Weber stated that chronoamperometry and Cotrell-type

[22] In *KSR*, the Supreme Court rejected the Federal Circuit's more stringent "teaching, suggestion, or motivation" test for obviousness in favor of a more flexible, common sense approach that allows courts greater leeway to grant summary judgment. Indeed, the Court stated that because obviousness is a question of law, "summary judgment is appropriate" where, as here, the scope of the claim, the level of skill in the art, and the content of the prior art are not in material dispute. *Id.* at 1745-46.

measurements were well known in the art and cites an additional five U.S. patents. (*Id*. at '225 chart, at 4.)[23] Any one of these nine references, all from the same field, can be combined with the Heller '225 reference to produce all the elements of claim 11. The inescapable conclusion is that claim 11 is obvious as a matter of law.[24] *KSR*, 127 S. Ct. at 1727.

E. The '745 Patent is Invalid Because the Term "Measurement Zone" is Indefinite and the Specification Does not Enable the Full Scope of the Claims.

The '745 Patent covers methods of using glucose monitors having a "measurement zone" of 1 microliter or less. (Ex. 1 ('745 Patent) at 61:39-63, 64:45-65:2, 65:37-66:15.) Each claim requires that this measurement zone: (1) be "positioned adjacent to the working electrode and counter electrode", (2) be "sized to contain a volume of no more than 1 microliter of the sample;" 3) contain an "analyte-responsive enzyme and a diffusible redox mediator;" and 4) hold the sample "in a non-flowing manner[.]" (*Id.* at 61:47-54.) The fact that Abbott relies on the size of the measurement zone in its attempt to avoid anticipation by the Gotoh reference further highlights the importance of the element. (Ex. 7 (Bard Rebuttal) at 21-22; Ex. 6 (Bard Dep.) at 413:24-414:5.) For the reasons detailed below, the '745 Patent is invalid as a matter of law because the term "measurement zone" is indefinite, and the patent fails to enable a person of skill in the art to construct or measure a "measurement zone" in the accused devices. (Weber Dec. Ex. 1 at 23:18-20.)

The '745 Patent discusses three different methods to determine blood glucose concentration: amperometry, coulometry, and potentiometry. (Ex. 1 ('745 Patent) at 6:12-13, 6:20-29, 7:19-21.) All of the asserted claims cover amperometric methods, and asserted claim 28 in particular is limited to amperometric methods. Similarly, the '745 Patent discusses two different configurations for the

[23] Dr. Bard's Report nowhere disputes any of Dr. Weber's conclusions on this issue. (Bard Rebuttal Report, Ex. 7.)

[24] If the Court concludes that the Heller '225 reference does not anticipate claim 8 because the '225 reference does not enable amperometry, then claim 8 is also obvious as a matter of law based on these same references.

working and counter electrodes: facing and co-planar. (*See id.* at Figs. 1 and 2.) None of the asserted claim is limited to either electrode arrangement, so all the asserted claims cover both. All of the accused devices have in common that they are amperometric and have co-planar electrodes.

The inventors of the '745 Patent were working primarily with coulometric sensors having facing electrodes. Abbott has identified no evidence that any of the named inventors ever conceived and reduced to practice a co-planar, amperometric system covered by the claims of the '745 Patent.[25] Abbott can cite to no lab notebooks, reports, analyses, memos, emails, or other documents that show that the research that led to the '745 Patent included testing or creation of a co-planar, amperometric device. It is therefore not surprising that Adam Heller (the first named inventor of the '745 Patent) testified at the time of his deposition that he had never before even *thought about* how to determine the measurement zone in a co-planar, amperometric system. (Ex. 25 (A. Heller Dep.) at 129:7-130:5, 132:8-12, 137:8-14.)

Abbott's expert, Dr. Bard, admits that the term "measurement zone" is not a term that is understood in the art. (*Id.* at 127:23-128:5.) So in order to understand how to construct and determine the volume of the measurement zone, a person of skill in the art must consult the specification of the '745 Patent. Dr. Bard concedes, however, that there is no discussion in the '745 Patent of how to determine the measurement zone in an amperometric sensor with co-planar electrodes. (Ex. 2 (Bard Dep.) at 20:12-13; 70:18 – 71:2, 117:23-118:11.) None of the exemplary devices in the '745 Patent are both amperometric and co-planar. (*Id*. at 187:21-189:3.) Dr. Bard admits that for the only figure in the '745 Patent that discusses a co-planar electrode arrangement, Figure 2, the sample chamber is erroneously described as being located in the "space between" the electrodes, as it would be in a facing electrode configuration. (Ex. 2 (Bard Dep.) at 65:13-66:4.) Dr.

[25] Abbott's expert agrees that there is nothing in the '745 Patent to indicate that the inventors had ever made or tested a co-planar system. (Ex. 2 (Bard Dep.) at 173:19-22.)

Bard does not offer any opinion as to what the '745 Patent teaches to a person of skill in the art about how the measurement zone should be determined in such a device. Rather, he relies exclusively on inventor deposition testimony. But the testimony Dr. Bard cites is inconsistent[26] and in any event, as Dr. Bard acknowledged, "the issue is what the patent teaches to one of ordinary skill in the art, not what the inventors said at their depositions." (Ex. 7 (Bard Rebuttal) at 13.) *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (holding that patent claims are of primary importance, and extrinsic evidence is less significant than intrinsic evidence in understanding the patent).

Stepping outside the express teaching of the '745 Patent, Dr. Bard testified based on his own knowledge and experience that the only way to determine the volume and location of the measurement zone in a co-planar amperometric device was to do a computer simulation using finite element analysis. (Ex. 2 (Bard Dep.) at 278:14-279:3; Ex. 6 (Bard Dep.) at 317:14-318:14, 319:16-321:21; *see also* Ex. 25 (A. Heller Dep.) at 129:24-131:25.) Dr. Bard admitted that the patent does not mention finite element analysis, let alone teach that finite element analysis should be used to determine the size and location of the measurement zone in a co-planar, amperometric device. (Ex. 2 (Bard Depo.) at 125:24-126:21, 127:23-129:9, 262:18-263:4, 284:21-285:22; Ex. 6 (Bard Dep.) at 312:19-313:19.)

The '745 Patent fails to enable a person of skill in the art to construct a co-planar, amperometric sensor that has a measurement zone meeting the requirements of the claims. The Federal Circuit has determined that in such a case, the patent is invalid as a matter of law. *See Automotive Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, Case Nos. 2006-1013 & 2006-1037, 2007 U.S. App. LEXIS 21271 (Fed. Cir. Sept. 6, 2007). In *Automotive Techs.*, the patent-in-suit covered a side-

[26] For example, Dr. Bard cites instances where both Ben Feldman and Ephraim Heller testified that the measurement zone in an amperometric sensor with co-planar electrodes is (1) the entire sample and (2) something less than the entire sample such as the area above and between the electrodes. (Ex. 7 (Bard Rebuttal) at 12-13.)

impact sensor to deploy an airbag in an automobile accident. 2007 U.S. App. LEXIS 21271, at *3. The patent included an extensive description of mechanical sensors that embodied the invention, but only a conceptual drawing and little description of an electronic sensor that satisfied the claims. *Id.* at *5-6. In particular, the patent included "only one short paragraph and one figure relate[d] to an electronic sensor," which did "little more than provide an overview of an electronic sensor without providing any details . . . concerning how the electronic sensor is built or operated." *Id.* at *20.

The claims were construed to cover both mechanical and electronic sensors, but the court found that the specification "fail[ed] to apprise one of ordinary skill how to make and use the electronic sensor." *Id.* at *21-22. On that basis, the court found that the claims were invalid as a matter of law. The court held that "in order to fulfill the enablement requirement, the specification must enable the full scope of the claims that includes both electronic and mechanical side impact sensors, which the specification fails to do." *Id.* at *28; *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371 (Fed. Cir. 2007) (patent invalid because the claims were construed to cover a fluid injector system for a replaceable syringe both with and without a pressure jacket, but the specification only enabled an injector with a pressure jacket).

The principle underlying the recent *Automotive Techs.* and *Liebel-Flarsheim* decisions is quite old. It dates back at least to the Supreme Court's decision in *O'Reilly v. Morse*, 56 U.S. 62 (1853). In that case, the Supreme Court considered the validity of claim 8 of Samuel Morse's patent on the telegraph which purported to cover any use of electromagnetism to print intelligible characters at a distance. *Id*. at 112. The Supreme Court held claim 8 was invalid because it covered more than the one way disclosed in the specification to print characters at a distance using electromagnetism. *Id.* at 117 ("for the method or process thus discovered, [Morse] is entitled to a patent. But he has not discovered … any other method…."). With respect to the specific invention disclosed in the specification, claim 8 "is outside of it, and the patentee claims beyond it." *Id*. at 119-20.

Similarly here, Abbott alleges that the asserted claims of the '745 Patent cover co-planar, amperometric devices. Yet the '745 Patent nowhere discusses how to construct or measure a measurement zone in a strip having co-planar electrodes which uses amperometry. The '745 Patent discloses a measurement zone for facing electrode configurations for coulometry and amperometry, but the claims go beyond that to cover co-planar arrangements for amperometry. The '745 Patent therefore fails to enable a person of ordinary skill in the art to practice the full scope of the asserted claims, and is invalid.

For similar reasons, the '745 Patent is indefinite because a person of skill in the art could not determine whether a co-planar, amperometric sensor, such as those accused of infringement in this case, has a measurement zone as required by the patent claims. 35 U.S.C. § 112, ¶ 2; *Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336 (Fed. Cir. 2002); *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1113 (Fed. Cir. 2002). The '745 Patent explicitly defines the term "measurement zone" as "a region of the sample chamber sized to contain only that portion of the sample that is to be interrogated during an analyte assay." (Ex. 1 ('745 Patent) at 7:8-10.) Despite this straightforward construction, as discussed above Abbott's expert has testified that there is no method discussed in the patent for determining what the measurement zone is in the accused devices. He admitted, for example, that a person designing a product having a 1.25 microliter sample chamber would have no ability, using the disclosure of the '745 Patent, to determine whether or not the "measurement zone" in the device was under 1 microliter. (Ex. 6 (Bard Dep.) at 312:19-313:19.)[27] Nor is the term "measurement zone" one that would be understood by a person of skill in the art outside the context of the patent. (Ex. 2 (Bard Depo.) at 127:23-128:5.) Accordingly, the term "measurement zone" is indefinite, and the claims invalid.

[27] Similarly, he testified that there would be no way to determine if a sensor met the background signal requirement. (Ex. 2 (Bard Depo.) 147:4-22.)

V. CONCLUSION

For the foregoing reasons, all of the asserted claims of the '745 patent are invalid.

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